REMARKS

In view of the above amendments and the following remarks, reconsideration of this application is respectfully requested.

Upon entry of the amendments presented herein, claims 32-53 will be pending. Claim 32 is hereby amended, and new claims 33-53 are hereby added. As set forth below, no new matter has been added by way of the amendments and newly added claims. Claims 1-21 are hereby canceled without prejudice, and claims 22-31 were previously canceled without prejudice.

Support for Claim Amendments and Newly Added Claims

Provided below is an explanation of the support in the originally filed specification or originally filed claims for the amendments to claim 32 and for newly added claims 33-53.

Claim 32 is hereby amended to recite the following preamble: "A method for ***maintaining intact, restoring, and/or increasing the number of cellular mitochondria in an elderly subject***" (emphasis added to indicate inserted text). Support for this amendment is found at least at pages 6-14 of the originally filed specification, and more particularly at page 8, lines 5-11, and page 9, lines 10-22 thereof.

Claim 32 is also hereby amended to recite the following step (emphasis added to show inserted text):

> administering to ***an elderly subject*** a therapeutically effective amount of a composition ***comprising, as active ingredients, the following:***
>
> ***(i) branched chain amino acids leucine, isoleucine, valine, and/or pharmaceutically acceptable derivatives thereof;***
>
> ***(ii) lysine and/or a pharmaceutically acceptable derivative thereof; and***
>
> ***(iii) at least one of:***
>
> ***(a) threonine or a pharmaceutically acceptable derivative thereof or***
>
> ***(b) one or more other essential amino acids selected from the group consisting of***

histidine, methionine, phenylalanine, and tryptophan, or pharmaceutically acceptable derivatives thereof,
whereby the number of cellular mitochondria in the elderly subject is maintained intact, restored, and/or increased.

Support for the above amendments with regard to the "composition" to be administered is found in original claims 1, 2, 5, and 9, and throughout the originally filed specification, particularly at page 4, line 26 to page 5, line 25.

Support for new claim 33 is found in original claims 3, 4, 5, and 7, and in the originally filed specification at page 4, line 26 to page 5, line 17.

Support for new claim 34 is found in original claims 10 and 11, and in the originally filed specification at page 5, lines 19-25.

Support for new claims 35-38 is found in original claims 12-14, and in the originally filed specification at page 5, line 27 to page 6, line 11.

Support for new claims 39-42 is found in original claims 16-20.

Newly added claim 43 is an independent claim directed to:

> 43. (New) A method for the treatment of apoptosis of mitochondrial origin in a subject, said method comprising:
> administering to a subject a therapeutically effective amount of a composition comprising, as active ingredients, the branched chain amino acids leucine, isoleucine, and valine, or pharmaceutically acceptable derivatives thereof,
> whereby the subject is treated for apoptosis of mitochondrial origin.

Support for new claim 43 is found in original claims 1, 2, 22, and 30, and in the originally filed specification at page 8, lines 5-11, and page 11, line 31 to page 12, line 21.

Support for new claim 44 is found in original claim 5.

Support for new claim 45 is found in original claim 9.

Support for new claim 46 is found in original claim 12.

Support for new claim 47 is found in original claim 5.

Support for new claim 48 is found in original claim 10.

Support for new claim 49 is found in original claim 13.

Support for new claim 50 is found in original claims 3, 4, 6, and 7, and in the originally filed specification at page 4, line 32 to page 5, line 17.

Support for new claim 51 is found in original claims 10 and 11, and in the originally filed specification at page 5, lines 19-25.

Support for new claim 52 is found in original claim 16.

Support for new claim 53 is found in original claims 19 and 20.

In view of the foregoing, applicant respectfully submits that no new matter has been added by way of the amendments to claim 32 and the addition of newly added claims 33-53. Therefore, entry of these amendments and new claims is respectfully requested.

Preliminary Matter— Search of the Prior Art

On page 13, at paragraph 16, of the current Office Action, the Examiner stated that it was not possible to conduct a complete prior art search with regard to claims 1-21. The Examiner acknowledged that a complete search was conducted for claim 32.

With regard to claims 1-21, the Examiner stated that applicant was required to provide clarification of the matters raised by the Examiner in order to allow the Examiner to conduct a complete prior art search for claims 1-21. In view of the cancellation of claims 1-21, applicant respectfully asserts that no such clarification is necessary.

Rejection Under 35 U.S.C. § 101

Claims 1-21 are rejected under 35 U.S.C. § 101 for being directed to a process that fails to recite any steps involved in the process.

This rejection is rendered moot in view of the cancellation of claims 1-21. Therefore, applicant respectfully submits that this rejection is improper and should be withdrawn.

Rejection Under 35 U.S.C. § 112, Second Paragraph

Claims 1-21 are rejected under 35 U.S.C. § 112, second paragraph, for indefiniteness for allegedly failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

This rejection is rendered moot in view of the cancellation of claims 1-21. Therefore, applicant respectfully submits that this rejection is improper and should be withdrawn.

Rejection Under 35 U.S.C. § 112, First Paragraph

Enablement

Claims 1-21 and 32 are rejected under 35 U.S.C. § 112, first paragraph, for allegedly lacking enablement.

With regard to claims 1-21, this rejection is rendered moot in view of the cancellation of those claims.

Regarding claim 32, this rejection is respectfully traversed in view of the above amendments to claim 32 and the following remarks.

At page 12 of the current Office Action, the Examiner acknowledges that the present application contains a working example with regard to "elderly subjects" (citing pages 6-14 of the originally filed specification). Because claim 32 has been amended to correspond to this working example, applicant respectfully submits that the rejection of claim 32 for alleged lack of enablement has been traversed.

While applicant believes that no further argument is needed to overcome this rejection as to claims 1-21 and 32, applicant provides further comment below in the event the Examiner wishes to analyze newly added claims 33-53 under the bases set forth to support the current enablement rejection of claims 1-21.

Claims 1-21 were rejected for lack of enablement for the alleged improper use throughout the specification and the claims of the terms "gram-moles," "gram molecular weights," and "on molecular weight basis."

In the current Office Action, the Examiner made the following statement in support of the enablement rejection:

> In the pharmaceutical art, the only unit of measurement that is useful for expressing a dosage amount of drug in a given composition that is related to the molecular weight of the drug is in terms of the molar content of the drug. This can be in number of moles or a concentration of moles/unit of solvent, i.e., molar

> concentration. However, a mole and a molecular weight are not synonymous.

(Office Action, at page 5, paragraph 12). While applicant agrees that a "mole" is not synonymous with a "molecular weight," applicant makes the following points to rebut the Examiner's ground for rejection.

It is well recognized in the pharmaceutical art that there are several units of measurement relating to molecular weight, including, for example: (i) moles (i.e., the mass of a substance in grams divided by the molecular weight of that substance); (ii) millimoles (i.e., the mass of a substance in milligrams divided by the molecular weight of that substance); and (iii) kilomoles (i.e., the mass of a substance in kilograms divided by the molecular weight of that substance). Other known units relating to molecular weight are micromoles, nanomoles, and picomoles.

Given a known amount in grams of a substance, the number of moles is obtained by dividing the known weight in grams by the molecular weight of the substance at issue. Thus, a number of moles relating to an amount of a given substance is always an expression of molecular weight.

Bearing the above in mind, the general wording "on molecular weight basis" appeared in the original claims. An amount of a substance expressed "on molecular weight basis" simply means, for a biochemist of ordinary skill, that he or she has to divide an amount in grams, milligrams, kilograms, etc., by the molecular weight of that substance. This is the reasons why, for instance, a mole is also called "gram molecular weight," as indicated occasionally in the original specification (it is not a case that a millimole is also called "milligram molecular weight" and a kilomole is also called "kilogram molecular weight").

Applicant also respectfully points out that the terms "gram-moles" and "gram molecular weight" are well known ***synonyms*** of "mole," although they are used more rarely. For the Examiner's convenience, applicant submits herewith three exhibits (i.e., **Annex 1**, **Annex 2**, and **Annex 3**) to show that "gram-mole" and "gram molecular weight" are, indeed, synonyms of "mole." **Annex 1** can be found at www.infoplease.com/ce6/sci/A0821497.html. **Annex 2** can be found at www.800mainstreet.com/6/0006-003-avogadro.htm. **Annex 3** can be found at dictionary.babylon.com/gram-mole.

Applicant also respectfully points out that the above concepts were deemed to be clear when considering the original disclosure of the invention, which includes the following relevant passage:

> Even though the ratios are expressed ***on the basis of molecular weight***, the ones indicated in the attached claims are applicable, in general terms, also in the case of calculation based on the weight in grams of the various amino acids indicated (bearing, however, in mind that the amount of lysine, expressed in grams ***rather than in moles***, may then be greater than the individual amounts of isoleucine and valine).

(Original Specification, at page 6, lines 26-31) (emphasis added).

Applicant also notes that the above-indicated passage also makes clear to the person of ordinary skill in the art that the various ratios indicated in the originally filed claims are also applicable to the case in which the amino acid contents are expressed in weight by grams, rather than on a molecular weight basis (i.e., in moles, gram-moles, or gram molecular weight).

Finally, Table 2 (at column 3) of the originally filed specification clearly shows that the indicated amounts are expressed in moles.

For the foregoing reasons, applicant respectfully submits that the rejection of claims 1-21 and 32 for alleged lack of enablement is improper and should be withdrawn.

Rejections Under 35 U.S.C. §§ 102(b) and (e)

Ozeki et al.

Claims 1, 2, 5, 9, 10, 12, and 21 are rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by U.S. Patent No. 5,036,052 to Ozeki et al.

This rejection is rendered moot in view of the cancellation of claims 1, 2, 5, 9, 10, 12, and 21. Therefore, applicant respectfully submits that this rejection is improper and should be withdrawn.

Germano

Claims 1, 2, 5, and 32 are rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by U.S. Patent No. 6,503,506 to Germano ("Germano").

With regard to claims 1, 2, and 5, this rejection is rendered moot in view of the cancellation of these claims.

With regard to claim 32, this rejection is respectfully traversed in view of the above amendments to claim 32 and the following remarks.

Germano is cited as allegedly teaching a method for making a nutritional supplement for treating chronic debilitating diseases to overcome conditions of oxidative stress, decreased lean muscle mass, and decreased energy production (e.g., mitochondrial failure). The Examiner further asserts that Germano teaches that the supplement can include amino acids such as leucine, isoleucine, valine, and lysine (citing the Abstract, and col. 8, line 45 to col. 9, line 10). In addition, the Examiner alleges that Germano teaches a method of treating that involves a patient taking two, one-bottle servings of the supplement (citing col. 8, line 49). However, the Examiner provides no further support or explanation as to how Germano teaches each and every element of claim 32.

As noted above, claim 32 has been amended to recite a "method for ***maintaining intact, restoring, and/or increasing the number of cellular mitochondria in an elderly subject***" (emphasis added to indicate inserted text). Nowhere does Germano teach or even suggest administering the amino acids recited in claim 32 in order to maintain intact, restore, and/or increase the number of cellular mitochondria in an elderly subject.

In addition, unlike the method of claim 32, Germano fails to disclose or suggest the use of "at least one of (a) threonine or a pharmaceutically acceptable derivative thereof or (b) one or more other essential amino acids selected from the group consisting of histidine, methionine, phenylalanine, and tryptophan, or pharmaceutically acceptable derivatives thereof." Further, Germano fails to disclose administering tyrosine and cyst(e)ine.

Therefore, it is clear that Germano cannot be used to support the present anticipation rejection of claim 32, because Germano fails to teach or disclose each and every element of the method of claim 32.

Similarly, although claim 43 is not subject to the current rejection based on Germano, it is also clear that Germano fails to disclose or even suggest a method for the treatment of apoptosis of mitochondrial origin in an animal as recited in new claim 43.

In view of the foregoing, applicant respectfully submits that the rejection of claims 1, 2, 5, and 32 based on Germano is improper and should be withdrawn.

Dioguardi (I)

Claims 1, 2, 5, 9, 10, 12, and 21 are rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by U.S. Patent No. 6,218,420 to Dioguardi.

This rejection is rendered moot in view of the cancellation of claims 1, 2, 5, 9, 10, 12, and 21. Therefore, applicant respectfully submits that this rejection is improper and should be withdrawn.

Conti et al. (I)

Claims 1, 2, 5, 9, 10, and 12 are rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by U.S. Patent Application Publication No. US-2004/0192756 to Conti et al.

This rejection is rendered moot in view of the cancellation of claims 1, 2, 5, 9, 10, and 12. Therefore, applicant respectfully submits that this rejection is improper and should be withdrawn.

Conti et al. (II)

Claims 1, 2, 5, 9, 10, and 12 are rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by U.S. Patent Application Publication No. US-2004/0157903 to Conti et al.

This rejection is rendered moot in view of the cancellation of claims 1, 2, 5, 9, 10, and 12. Therefore, applicant respectfully submits that this rejection is improper and should be withdrawn.

Rejections for Nonstatutory Obviousness-Type Double Patenting

Dioguardi (I)

Claims 1, 2, 5, 9, 10, 12, and 21 are rejected for nonstatutory obviousness-type double patenting as allegedly being unpatentable over claims 1-9 of U.S. Patent No. 6,218,420 to Dioguardi.

This rejection is rendered moot in view of the cancellation of claims 1, 2, 5, 9, 10, 12, and 21. Therefore, applicant respectfully submits that this rejection is improper and should be withdrawn.

Conti et al. (III)

Claims 1, 2, 5, 9, 10, 12, and 21 are *provisionally* rejected for nonstatutory obviousness-type double patenting as allegedly being unpatentable over claims 16-35 of co-pending U.S. Patent Application Serial No. 12/104,722 to Conti et al.

This rejection is rendered moot in view of the cancellation of claims 1, 2, 5, 9, 10, 12, and 21. Therefore, applicant respectfully submits that this rejection is improper and should be withdrawn.

Conti et al. (IV)

Claims 1, 2, 5, 9, 10, 12, and 21 are *provisionally* rejected for nonstatutory obviousness-type double patenting as allegedly being unpatentable over claims 23-54 of co-pending U.S. Patent Application Serial No. 10/486,141 to Conti et al.

This rejection is rendered moot in view of the cancellation of claims 1, 2, 5, 9, 10, 12, and 21. Therefore, applicant respectfully submits that this rejection is improper and should be withdrawn.

Conti et al. (V)

Claims 1, 2, 5, 9, 10, 12, and 21 are *provisionally* rejected for nonstatutory obviousness-type double patenting as allegedly being unpatentable over claims 9, 10, and 12-29 of co-pending U.S. Patent Application Serial No. 10/480,774 to Conti et al.

This rejection is rendered moot in view of the cancellation of claims 1, 2, 5, 9, 10, 12, and 21. Therefore, applicant respectfully submits that this rejection is improper and should be withdrawn.

Dioguardi (II)

Claims 1, 2, 5, 9, 10, 12, and 21 are *provisionally* rejected for nonstatutory obviousness-type double patenting as allegedly being unpatentable over claims 33-54 of co-pending U.S. Patent Application Serial No. 10/332,236 to Dioguardi.

This rejection is rendered moot in view of the cancellation of claims 1, 2, 5, 9, 10, 12, and 21. Therefore, applicant respectfully submits that this rejection is improper and should be withdrawn.

CONCLUSION

Claims 32-53 are now under consideration in this case. In view of the foregoing, applicant respectfully submits that the claims of the present application are in condition for allowance and such allowance is earnestly solicited.

If any unresolved issues remain that might prevent the prompt allowance of the present application, the Examiner is respectfully encouraged to contact the undersigned at the telephone number listed below to discuss these issues.

Submitted herewith is via EFS-Web is payment for a two-month extension of time under 37 C.F.R. § 1.17(a)(2) ($490, Large Entity). The Commissioner is hereby authorized to charge any fees that may have been overlooked, or to credit any overpayments of fees, to Deposit Account No. 08-1935.

Respectfully submitted,

HESLIN ROTHENBERG FARLEY & MESITI P.C.

By: **/Andrew K. Gonsalves/**

Dated: **November 26, 2008**

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